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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,246	03/17/2005	Byong-Sung Kwak	20345/0202513-US0	2511
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DARBY & DARBY P.C. P.O. BOX 770 Church Street Station New York, NY 10008-0770			EXAMINER OH, TAYLOR V	
			ART UNIT 1625	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/528,246	<b>Applicant(s)</b> KWAK ET AL.	
	<b>Examiner</b> Taylor Victor Oh	<b>Art Unit</b> 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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## **Final Rejection**

### **The Status of Claims**

Claims 1-2, and 4-16 are pending.

Claims 1-2, and 4-16 are rejected.

### **Claim Objections**

Claim 16 is objected to because of the following informalities:

In claim 16, the phrase “the acid additive ” is recited. This expression is improper; it should be changed to “the acid catalyst ” . Appropriate correction is required.

### **Claim Rejections - 35 USC § 112**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of Claims 1-2, 4, 6-14, and 16 under 35 U.S.C. 112, first paragraph, has been withdrawn due to the modification made in the claims.

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The rejection of Claims 1-16 under 35 U.S.C. 112, first paragraph, has been maintained because some claims are still unmodified according to the examiner's suggestion.

**Claim Rejections - 35 USC § 102**

Applicants' argument filed 11/28/2007 have been fully considered but are not persuasive.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**The rejection of Claims 1, 7, 9,12, and 14 under 35 U.S.C. 102(a) as being anticipated clearly by Kwak et al (WO 02/10147 A1) has been changed to the rejection of Claims 1-2, and 4-16 under 35 U.S.C. 103(a) as being unpatentable over Kwak et al (WO 02/10147 A1) in view of Aslam et al (Kirk –Othermer Encyclopedia of Chemical Technology, 12/4/2000, p.477)**

The rejection of Claims 1, 7, 9,12, and 14 under 35 U.S.C. 102(a) as being anticipated clearly by Kwak et al (WO 02/10147 A1) has been changed to the rejection of Claims 1-2, and 4-16 under 35 U.S.C. 103(a) as being unpatentable over Kwak et al (WO 02/10147 A1) in view of Aslam et al (Kirk –

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Othermer Encyclopedia of Chemical Technology, 12/4/2000, p.477) due to the revised claims in the amendment.

### **Claim Rejections - 35 USC § 103**

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been

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obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, and 4-16 under 35 U.S.C. 103(a) as being unpatentable over Kwak et al (WO 02/10147 A1) in view of Aslam et al (Kirk –Othermer Encyclopedia of Chemical Technology, vol. 10, 12/4/2000, p.477).

Kwak et al discloses the continuous process for producing optically pure (s)-beta-hydroxy-gamma-butyrolactone in the following abstract (see abstract page):

**(57) Abstract:** Disclosed is a process for the production of optically pure (S)-beta-hydroxy-gamma-butyrolactone through the hydrogenation of substituted carboxylic acid derivatives. A solution containing 1 to 50 % by weight of a substituted carboxylic acid derivative is fed at a WHSV of 0.1 to 10 h<sup>-1</sup>, to a fixed bed reactor which is filled with a catalyst and maintained at a reaction temperature of 50 to 550 °C under a halogen partial pressure of 15 to 5,500 psig. The catalyst is composed of a noble metal as a catalytically effective ingredient which is impregnated in an inorganic oxide as a support. The molar ratio of the hydrogen to the substituted carboxylic acid derivative is maintained at a molar ratio of 1:1 to 10:1. The process can produce optically pure (S)-beta-hydroxy-gamma-butyrolactone with higher purities at higher yields than can conventional techniques. In addition to being relatively simple and environmentally friendly, the process is so economically favorable as to apply to industrial production.

Furthermore, the esterification reaction is carried out at 50 to 150<sup>0</sup> C in the presence of a catalyst such as a solid acid of a sulfonate-substituted strong acid resin (see page 7, lines 1-2).

## EXAMPLE 1

## Preparation of Catalyst

resulting ruthenium-supported catalyst was sintered at 550 °C for 6 hours under the air atmosphere in a muffle furnace. The catalyst was found to have a ruthenium content of 3.0 % by weight as measured by fluorescent X-ray analysis.

(see page 12, the first paragraph).

## Examples of suitable noble metal catalyst

include Ni, Pd, Pt, Rh, Ir, Ru, Os and mixtures thereof with preference to Ru. The catalytically active ingredient may be used in a bare form or in a combination with a support. In the latter case, the noble metal is impregnated on the support. Suitable as a support is an inorganic oxide selected from the group consisting of alumina, silica, silica-alumina, zirconia, titania, zeolite and molecular sieves. Of them, silica is most preferred.

(see page 9, the first paragraph).

### Continuous Preparation of Dimethyl (S)-Malate

In an automatic high-pressure reactor made of stainless steel 316 was filled 25 g of a solid acid catalyst. After being purged with nitrogen, the inside of the reactor was heated from room temperature to 84 °C and maintained at a pressure of 100 psig. L-malic acid was dissolved in 8 equivalents of methanol and the resulting solution was fed at a WHSV of 4.0 h<sup>-1</sup> into the reactor to produce the title compound at a yield of 90 %: Conversion 99 %. Selectivity 99 %.

(see page 12, the second paragraph).

The effluent from the reactor was distilled in vacuum to separate at a separation yield of 90 % dimethyl (S)-malate which was 99.8 % in purity and 99.9 % in optical purity. The preparation could be effected in a batch type. In this case, the reaction period of time was set to be 2 to 4 hours.

(see page 12, the first paragraph).



### Continuous Preparation of (S)-Beta-Hydroxy-Gamma- Butyrolactone

In an automatic, stainless-steel 316, high pressure reactor (inner diameter 2.52 cm x length 60 cm) was filled 50 g of the catalyst prepared in Example 1. The catalyst was converted to a reduced state by raising the temperature at a rate of 1 °C per min to 350 °C and maintained at this temperature for 6 hours in a hydrogen atmosphere. After being cooled, the inside of the reactor was purged with nitrogen gas. While the inside of the reactor was heated at a rate of 1 °C per min to 145 °C from room temperature, hydrogen was fed at a rate of 100 sccm. The hydrogen was added at an amount twice as much as necessary for the reaction. The dimethyl (S)-malate prepared in Example 2 was dissolved in water to give a 30 wt% solution. This dimethyl (S)-malate solution was fed under the conditions shown in Table 1, below. Reaction products were taken every 9 hours and analyzed by gas

chromatography using a flame ionization detector

(see page 13, the second paragraph).

TABLE 2

Example		Conversion.	Selectivity
No.	Solvent	(%)	for (S)- HGB* (%)

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9	30% H <sub>2</sub> O	92.0	85.5
10	20% H <sub>2</sub> O	94.0	72.0
11	10% H <sub>2</sub> O	95.0	78.0
12	10% i-PrOH	72.5	54.2

\* (S)-beta-hydroxy-γ-butyrolactone

(see page 15, the table 2).

However, the instant invention differs from the prior art in that the inorganic acid catalyst is unspecified in the esterification reaction process; its mount is also unspecified in the process.

Aslam et al discloses the use of the various catalysts in the esterification process as shown below (see page 477, from the middle to the last paragraph) :

**2.5. Catalysts.** The choice of the proper catalyst for an esterification reaction is dependent on several factors (43-46). The most common catalysts used are strong mineral acids such as sulfuric and hydrochloric acids. Lewis acids such as boron trifluoride, tin and zinc salts, aluminum halides, and organo-titanates have been used. Cation-exchange resins and zeolites are often employed also.

In laboratory preparations, sulfuric acid and hydrochloric acid have classically been used as esterification catalysts. However, formation of alkyl chlorides or dehydration, isomerization, or polymerization side reactions may result. Sulfonic acids, such as benzenesulfonic acid, *p*-toluenesulfonic acid, or methanesulfonic acid, are widely used in plant operations because of their less corrosive nature. Phosphoric acid is sometimes employed, but it leads to rather slow reactions. Soluble or supported metal salts minimize side reactions but usually require higher temperatures than strong acids.

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*Acid-Regenerated Cation Exchangers.* The use of acid-regenerated cation resin exchangers (see ION EXCHANGE) as catalysts for effecting esterification offers distinct advantages over conventional methods. Several types of cation-exchange resins can be used as solid catalysts for esterification (47,48). In general, the strongly acidic sulfonated resins comprised of copolymers of styrene, ethylvinylbenzene, and divinylbenzene are used most widely. With the continued improvement of ion-exchange resins, such as the macroporous sulfonated resins, esterification has become one of the most fertile areas for use of these solid catalysts. With low molecular weight acids and alcohols, in most cases the resin structure has minimal effect on the yield or kinetics of the esterification as long as the catalyst contains strongly acidic groups. The kinetics in batch and tubular reactors of the esterification of 1-butanol with acetic acid catalyzed by a macroporous sulfonated polystyrene exchange resin have been studied. The catalytic activity was dependent on the water content of the resin and the rate determining step is the surface reaction of the chemisorbed acid and adsorbed alcohol (49).

Regarding the amount of the inorganic acid used in the process, the limitation of a process with respect to ranges of pH, time, concentration does not impart patentability to a process when such values are those which would be determined by one of ordinary skill in the art in achieving optimum operation of the process. The concentration of the inorganic acid is well understood by those of ordinary skill in the art to be a result-effective variable, especially when attempting to control selectivity of the process.

Kwak et al expressly discloses the continuous process for producing optically pure (S)-beta-hydroxy-gamma-butyrolactone by using the esterification step in the presence of the solid acid; furthermore, Aslam et al does point out that there is an equivalence between the sulfuric acid or hydrochloric acid and the solid acid catalyst in the esterification process. Therefore, it would have been obvious to the skilled artisan in the art to be motivated to incorporate the Aslam et al sulfuric acid catalyst into the Kwak et al process as an alternative to the

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solid acid catalyst. This is because the skilled artisan in the art would expect such a manipulation to be successful and feasible as guidance shown in the prior art.

#### Applicants' Argument

Applicants argue the following issues:

- a. Since claim 1 has been amended to include the limitation of claim 3 so that the claims are not anticipated by the Kwak et al prior art.

Applicants' arguments have been noted, but the arguments are not persuasive.

First, regarding the applicants' argument, the Examiner has noted applicants' arguments. However, there are still some issues present in the claimed invention. Thus, the new 103 rejection based on the new prior art was applied as shown in the above. Therefore, applicants' argument is not persuasive.

#### **Conclusion**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Taylor Victor Oh, MSD,LAC  
Primary Examiner  
Art Unit: 1625

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2/13/08